

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES WASHINGTON, D.C. 20460

January 13, 1999

MEMORANDUM

SUBJECT: **Phosmet**: Response to comments received on the document entitled *The ORE aspects*

of the HED Chapter for the RED for Phosmet, dated May 12, 1998 [Case #838564, PC

Code 059201, DP Barcode D252048]

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Comments were received in two letters, one from the Gowan Chemical Company and the other from the Schering-Plough Animal Health Corporation (herein referred to as SPAH). Only the Occupational and Residential Exposure aspects of the RED comments are addressed herein.

1. Background Information

This memo was developed based on the information contained in the following referenced documents:

- The ORE aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Phosmet, Case #838564, PC Code 059201, DP Barcode D236026; Dated May 12, 1998; From Jeff Dawson (Chemist, OPP/HED/RRB-1) to Christina Swartz (Chemist, OPP/HED/RRB-1).
- Phosmet: Human Health Risk Assessment and Supporting Documentation for the RED, DP Barcode D236026, Dated October 30, 1998; From Christina Swartz (Chemist, OPP/HED/RRB-1) to Linda Werrell (OPP, Special Review and Reregistration Division).
- Gowan Chemical Company 30 day Response to HED RED Preliminary Risk Assessment for Phosmet dated October 30, 1998; faxed December 14, 1998; From Elizabeth Codrea, Regulatory Product Manager at Gowan to Linda Werrell, Chemical Review Manager, U.S. EPA, Office of Pesticide Programs, Special Review and Reregistration Division.
- Initial Schering-Plough Animal Health Corporation Response to OPP Preliminary Health Assessment for Phosmet; faxed December 11, 1998; From Iain Weatherston, Senior Regulatory Consultant at Technology Sciences Group, Inc. (an agent for Schering-Plough Animal Health Corporation) to Linda Werrell, Chemical Review Manager, U.S. EPA, Office of Pesticide Programs, Special Review and Reregistration Division.

2. Rebuttal Comments and Agency Responses to Gowan December 14, 1998 Letter

The letter submitted to the Agency contained comments focused on all areas of the risk assessment included in the Agency's May 1998 document. The comments focused on the dietary exposure and hazard identification aspects of the RED chapter are not addressed in this rebuttal response. The comments focused on the Occupational and Residential exposure (ORE) aspects of the draft RED chapter are addressed herein.

The format of the letter references specific aspects of the draft RED chapter by page number and then provides excerpts of the draft Agency RED chapter followed by the Gowan response. In order to facilitate review of this document, each specific Gowan comment in its entirety is reproduced below followed by the Agency response to the comment.

A. Gowan ORE Comment 1: RED page 3(Summary/Conclusions)

i. Gowan Comment 1

EPA discusses reentry intervals for citrus, pears, and grapes in both the HED October 30, 1998 document and in the OREB May 12, 1998 supporting document. We point out that citrus is not a currently registered use for phosmet. In addition, it should be noted that the calculated REIs are very likely, *a priori*, in error since default transfer coefficients were utilized in the preliminary risk assessment. Highly refined data, which will permit great precision in reentry risk assessments are currently being generated by the Agricultural Reentry Task Force, of which Gowan is a member.

Last line - typo "the Agency will conduct and aggregate..."

ii. Agency Response to Gowan Comment 1

The Agency only addressed citrus exposures in the postapplication aspects of the exposure and risk assessment. The specific EPA Reg. No. that was referenced in the exposure/risk assessment was 10163-166. This label contained an application rate of 15 lb ai/acre. The Agency acknowledges this comment and will modify the risk assessment when labels are revised to remove the citrus use.

The Agency does not concur that the calculated REIs are, *a priori*, in error because default transfer coefficients were used for the assessment. The transfer coefficients for citrus, grapes, pears, and low growing row crops are indeed based on the current Agency default values. It should be noted that these values are based on published data and the otherwise best data available. These values are also similar to those used by other regulatory agencies in lieu of chemical- and activity- specific data. The Agency applauds the work of the Agricultural Reentry Task Force and will refine current risk assessments as additional, more refined data become available. In the interim, however, the Agency is committed to protecting human health through the use of the established default values. It should also be noted that in a risk assessment submitted by Gowan Corporation (Phosmet Dermal Passive Dosimetry Addendum to MRID 404253-01 submitted on December 14, 1992, author E. Codrea, EPA MRID 425958-01), the same default transfer coefficient of 10,000 cm² was used to calculate REIs for

citrus, pears, and grapes that was used by the Agency in the completion of the RED chapter. The major differences in the Agency versus Gowan calculations were the endpoint (a 100 mg/kg/day 21 day dermal study endpoint used by Gowan versus a 1.1 mg/kg/day oral endpoint with a 20 percent dermal absorption factor and by the Agency) and the use of different uncertainty factors (100 by Gowan and 300 by the Agency).

The typographical error noted by Gowan will also be revised.

B. Gowan ORE Comment 2: RED page 4 (Data Requirements - Occupational and Residential Exposure)

i. Gowan Comment 2

Clarification is necessary for EPA's statement that:

"... phosmet registrants must develop a strategy to generate chemical-specific transferable residue data to be used in conjunction with the Agricultural Reentry Task Force. The registrants may be required to develop additional chemical-specific data in conjunction with the work of the Outdoor Residential Exposure Taskforce (*sic*) (ORETF)."

It is not clear what is meant by the term "chemical-specific transferable residue data". As noted earlier in these comments, the Agricultural Reentry Taskforce, of which Gowan is a member, is generating generic transfer coefficient data for an extensive range of crop reentry activities. As noted in both the HED October 30, 1998 preliminary risk assessment and in the OREB May 12, 1998 supporting document, the Agency has acceptable foliar dislodgeable residue studies for phosmet. Clarification is required of this apparent new requirement.

Related to the above, on page 43 of the OREB May 12, 1998 support document, reference is made to extending this new requirement to Zeneca, the previous phosmet basic registrant. All Zeneca registrations with the exception of Prolate Technical Livestock Insecticide were transferred to Gowan Company on April 17, 1991. This product was subsequently transferred to Gowan on September 12, 1996 (EPA Reg. No. 10163-227).

Regarding issues associated with the Outdoor Residential Exposure Taskforce, we note that the ORETF, as outlined in the original March 3, 1995 data call-in (DCI) is developing exposure data for home lawn, grass, and turf uses. Gowan Company is, in fact, a member of this taskforce; however, it should be noted that phosmet was not listed in the DCI as an active ingredient subject to the data requirements. Gowan Company's home and garden registrations, as cited in the May 12, 1998 OREB support document are EPA Reg. Nos. 10163-167, 10163-170, 10163-171, and 10163-173. None of these products are labeled for home lawn, grass, or turf uses.

ii. Agency Response to Gowan Comment 2

The Agency can clarify the comments made above with regard to both the ARTF, the ORETF, and each related Data Call-In. The Agency stresses that referenced aspects of the Agency RED document do not create "an apparent new data requirement." The DCI for agricultural reentry data required the development of dislodgeable foliar residue (DFR) study protocols for all effected active ingredients in addition to the "generic" data to be generated by the taskforce itself. A database is required that can be used to assess how regional, formulation, and crop differences (as well as other factors) effect postapplication exposures. In response to the DCI, the ARTF working in conjunction with regulatory and scientific personnel from the U.S. EPA and other agencies, did not develop specific protocols. Instead, a strategy was instituted based on (1) development of a generic DFR protocol (and associated field notebook and reporting format) to be used by task force members to ensure consistency in the data generation process and (2) development of a strategy specific to each active ingredient that would explicitly illustrate how DFR data are to be generated (i.e., what studies) and how the data are to be bridged whenever required (e.g., across regions, similar crops, etc.). Strategies for each active ingredient are also required to address how the DFR data are to be generated by stipulating other issues such as submission dates and other regulatory requirements. The agency has provided guidance for developing these kinds of strategies in the Draft Series 875 - Occupational and Residential Exposure Test Guidelines, Group B - Postapplication Exposure Monitoring Test Guidelines (Part B, Chapter 2 - Study Design). These strategies can also serve as a guide for data generation and to illustrate the use patterns of the chemical active ingredient (e.g., serve as a basis for communication between the Agency and effected registrants on use pattern issues).

The Agency incorporated into the RED chapter the dislodgeable foliar residue data for phosmet on oranges, grapes, and pears included in EPA MRID 404253-01 (*Dislodgeable Residue Dissipation and Reentry Interval Calculations For Crops Treated with Products Containing Phosmet*, October 22, 1986). [It should also be noted that the Agency used the grape data to bridge low-growing row crop exposures (e.g., vegetable uses) in lieu of crop-specific data.] This study was accepted by the Agency in a 1991 review. However, phosmet can be used on a variety of crops other than oranges, grapes, and pears where there is a substantial potential for postapplication exposure and where no chemical-specific DFR data exist (e.g., ornamentals, cotton, and blueberries). The aforementioned strategy is to serve as the basis for defining the potential need for additional data or for determining how these existing data are to be bridged.

The comment pertaining to the identity of the basic registrants is acknowledged by the Agency. The Agency will remove all references to the Zeneca Corporation in any document.

With regard to the activities of the ORETF and the use of phosmet in a residential environment, the Agency acknowledges that phosmet was not included in the list of active ingredients effected by the turf chemical DCI and also that the current scope of the ORETF is for turf chemicals. However, there has been a discussion within the ORETF Joint Regulatory Committee that the scope of the taskforce might be modified to include other outdoor residential uses such as in home gardens and on ornamentals. If this indeed occurs, it is likely that the member companies will address any data requirements through the taskforce and not on an individual basis. Therefore, the comments provided

by Gowan on this issue are correct. However, it is likely that further effort may be needed to support the non-turf residential uses of phosmet which is the reason that the referenced comments were included in the RED document. It should also be noted that the Agency indicated in the referenced RED chapter that "studies **may be completed** [by the ORETF] to enable the Agency to evaluate outdoor residential exposures due to contact with treated **plants if the scope of the ORETF is expanded** to include home garden pesticide uses." Additionally, it should also be noted that, particularly under the requirements of FQPA, that the Agency would be interested in any residential exposure scenarios regardless of taskforce membership or the scope of the turf DCI. The Agency recommends review of the residential exposure scenarios of concern included in the *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment* (December 11, 1997). This document clearly addresses use patterns that are similar to the residential uses of phosmet.

C. Gowan ORE Comment 3: Page 10 (Occupational and Residential Exposure/Risk)

i. Gowan Comment 3

The Agency states:

"Post-application exposures include agricultural harvesters or children playing on a treated lawn or with a treated animal."

As noted above, phosmet is not registered for use on lawns.

ii. Agency Response to Gowan Comment 3

The reference above has been taken out of context by Gowan. This reference was included in the RED for illustrative purposes only and was not intended to directly relate to phosmet use patterns. The examples provided are the most commonly noted examples of occupational and postapplication exposure scenarios. The Agency will modify the examples by removing "children playing on a treated lawn" and will replace the sentence with "Post-application exposures include agricultural harvester dermal exposures; oral, dermal, and inhalation exposure received from playing with treated dogs; and the oral (through treated soil ingestion), inhalation, and dermal exposures received from treated ornamentals or garden plants." With regard to the lawn use registration comment, the Agency acknowledged that phosmet is not registered on lawns and discussed the other issues surrounding lawn uses in the response to comment 2 above.

3. Rebuttal Comments and Agency Responses to SPAH December 11, 1998 Letter

The letter submitted to the Agency contained comments focused on all areas of the risk assessment included in several documents released by the Agency including the May 1998 Occupational and Residential Exposure Assessment and the October, 1998 Human Health Risk Assessment RED document. The comments focused on the dietary exposure and hazard identification aspects of the RED chapter are not addressed in this rebuttal response. The comments focused on the Occupational and Residential exposure (ORE) aspects of both documents are addressed herein.

For clarity, each specific SPAH comment is reproduced in its entirety followed by the Agency response to the comment. [Note: SPAH refers to the Schering Plough Animal Health Corporation.] The letter also includes "normal text" and "italicized" comments representing errors and 60 day comments, respectively, as indicated in the SPAH letter. All of the comments, whether error corrections or 60 day comments have been addressed in this document.

A. SPAH ORE Comment 1: Introductory Comment on Page 1

i. SPAH Comment 1

This document as it applies to the animal health uses is so replete with errors and inaccuracies that is casts serious doubts on the validity of the conclusions since that are no phosmet products registered for use:

- a] on cats
- b] on livestock as a dip vat insecticide
- c] on livestock, in a dust bag
- d] as an OTC dip product for dogs
- e] as a dog collar (see below)

ii. Agency Response to SPAH Comment 1

The Agency acknowledges any label cancellations and will modify the risk assessment as appropriate. It should also be noted that several iterations of these cancellation comments are repetitive throughout the SPAH letter. Each will be addressed individually as appropriate.

Specific to these comments, the Agency did reference cats throughout the discussion of the pet care products. The Agency will remove any reference to cats. It should also be noted that the pet use product exposure and risk assessment was completed only for dogs (5 and 120 pound animals) and that the risks were unacceptable in all cases. The deletion of cats from the risk assessment does not impact the interpretation or the results of the original risk assessment.

All references to the dip vat, dust bag, OTC dip for dogs, and dog collar will be removed from the risk assessment as appropriate.

It should be noted that the SPAH comment regarding the validity of the risk assessment is acknowledged for the specific uses noted (i.e., they are not valid if the use has been deleted). Other than the deleted uses, the comment is not applicable as the phosmet exposure and risk assessment is based on short- and intermediate-term endpoints. Also, no aggregate or cumulative assessment has been completed to date.

B. SPAH ORE Comment 2: Summary (page 2, bullet 1)

i. SPAH Comment 2

It is stated that the assessment is based on nineteen product labels, of these eight are of products used in animal health, however three of the products have been canceled and hence their labels should not have been used in the assessment. The canceled products are:

773-077	Prolate 5 Dust voluntarily canceled July 1997
773-079	Del-Phos Sponge-On Dip For Dogs voluntarily canceled May 1998
2724-277	Zoecon RF 50 Dust for Dogs voluntarily canceled July 1998

Also, after discussions with Dr. Steve Spaulding at Wellmark International, Bensenville IL, it has been learned that Wellmark International will notify the Agency of cancellation of 2724-279 Zoecon RF 156 Collar for Dogs, since this is the only dog collar product the impact on the assessment should be significant.

ii. Agency Response to SPAH Comment 2

The Agency acknowledges any product cancellations and will revise the risk assessment to reflect these labeling changes. It should be noted, however, that the EPA ORE Risk Assessment document that is reviewed in this letter by SPAH was completed on May 12, 1998 and that two of the three voluntary cancellations occurred simultaneously or after the EPA document was completed (i.e., May or July, 1998). The Agency stresses that any existing label will be included in the exposure and risk assessment until cancellation procedures are finalized. Also, please note the discussion of impacts of use revisions on the risk assessment in the *Agency Response to SPAH Comment 1* above.

C. SPAH ORE Comment 3: Summary (page 2, bullet 2)

i. SPAH Comment 3

Throughout the document there are numerous references to "pets" and "dogs and cats," any reference to the phosmet use on cats is erroneous - at this time there is no phosmet product labeled for use on cats. Wellmark International [Sandoz] did have indications for cat use on the Vet-Kem Kernolate label, however this use was canceled on March 2, 1998. Considering that the pet cat population in the United States accounts for more than 50% of the dog/cat combined population, any assessment based on this combined population is in error.

ii. Agency Response to SPAH Comment 3

All references to cats will be deleted and the term "pets" will either be deleted and replaced with "dogs" or it will be defined to indicate that it only refers to dogs. As indicated above, the Agency recognizes product cancellations and will revise the risk assessment as appropriate. The Agency would also like to indicate that the deletion of cats from the risk assessment does not impact the results of the assessment as it was based solely on the treatment of dogs (i.e., large and small animals) in short- and intermediate-term exposure scenarios.

D. SPAH ORE Comment 4: Summary (page 2, bullet 3)

i. SPAH Comment 4

Throughout the document there are numerous references to the use of phosmet products in livestock dip vats. Currently, there are no actual product labels in use carrying directions for the phosmet products to be used as livestock dips. The stamped approval label for SPAH's Prolate 1E Emulsifiable Liquid [773-076] sold under the name Del-Phos Emulsifiable Liquid is identical to the label currently on the product and does not include a livestock dip vat use. The current product label for Wellmark International's Zoecon RF-43 Emulsifiable Liquid [2724-262] sold under the brand name Starbar GX-118 also does not carry any directions for use in dip vats. *The latest stamped approval label for this product [September 17, 1998] however does have provisions for use as a livestock dip vat insecticide. Discussions with Dr. Steve Spaulding at Wellmark International, Bensenville, IL have resulted in the company indicating that they will submit to the Agency amendment for the removal of dip vat uses from the label.*

ii. Agency Response to SPAH Comment 4

The Agency acknowledges any product cancellations and will revise the risk assessment to reflect these labeling changes. The Agency stresses that any existing label for livestock dipping vats will be included in the exposure and risk assessment until cancellation procedures are finalized.

E. SPAH ORE Comment 5: Detailed Items, Page 3 (Page 3 of letter)

i. SPAH Comment 5

Page 3: the table and the text above it needs to be amended, based on the information given in point one in the summary.

ii. Agency Response to SPAH Comment 5

The risk assessment will be modified as appropriate based on label cancellations and other regulatory activities. The Agency stresses that any existing labels will be included in the exposure and risk assessment until cancellation procedures are finalized.

F. SPAH ORE Comment 6: Detailed Items, Page 4 (Page 3 of letter)

i. SPAH Comment 6

Page 4: "fleas" should be added to the list of pests in the "For Direct Animal Treatment" list.

ii. Agency Response to SPAH Comment 6

"Fleas" will be added to the list.

G. SPAH ORE Comment 7: Detailed Items, Page 5 (Page 3 of letter)

i. SPAH Comment 7

Page 5: In the list of both occupational and homeowner/residential "use sites" under pets, "cats" should be removed.

ii. Agency Response to SPAH Comment 7

"Cats" will be removed. The Agency stresses that this action will not impact the pet use risk assessment.

H. SPAH ORE Comment 8: Detailed Items, Page 6 (Page 3 of letter)

i. SPAH Comment 8

Page 6: Application Parameters. all references to dip vats should be removed.

ii. Agency Response to SPAH Comment 8

The Agency refers to Section 3.D above where it is acknowledged that a dip vat use still exists but will likely be canceled. As a result, the Agency will not remove any dip vat use from the risk assessment until all cancellations of such products become official.

I. SPAH ORE Comment 9: Detailed Items, Page 7 (Page 3 of letter)

i. SPAH Comment 9

Page 7, Application parameters (cont.)

Farm Animal Dust: there are no registered dust bag use products.

Pet Dust: there are no dust products labeled for use on cats.

Pet Collar: again this was a dog product and not a dog and cat product, see above, Wellmark will cancel this product.

ii. Agency Response to SPAH Comment 9

The Agency acknowledges any product cancellations and will revise the risk assessment to reflect these labeling changes. The Agency stresses that any existing label for pet collars will be included in the exposure and risk assessment until cancellation procedures are finalized.

"Cats" will be removed. The Agency stresses that this action will not impact the pet use risk assessment.

J. SPAH ORE Comment 10: Detailed Items, Page 11 (Page 3 of letter)

i. SPAH Comment 10

Page 11: Handler Risk Assessment, Assumptions and Factors, second paragraph: 1,000 gallons for cattle dipping should be removed.

ii. Agency Response to SPAH Comment 10

The Agency refers to Section 3.D above where it is acknowledged that a dip vat use still exists but will likely be canceled. As a result, the Agency will not remove any dip vat use from the risk assessment until all cancellations of such products become official.

K. SPAH ORE Comment 11: Detailed Items, Page 15 (Page 3 of letter)

i. SPAH Comment 11

Page 15: Occupational Handler Risk Assessment, Scenarios 8, 13, and 16 should be removed. Homeowner Handler Risk Assessment Scenarios, Numbers 2 and 3 should be removed.

ii. Agency Response to SPAH Comment 11

Occupational scenarios 8, 13, and 16 are for livestock dip vats, dusting an animal, and using a dog collar, respectively. The Agency refers to Sections 3.B, 3.D, and 3.I above where it is acknowledged by SPAH that dip vat and dog collar uses still exist, but that they will likely be canceled. As a result, the Agency will not remove these uses from the risk assessment until all cancellations of such products become official. Additionally, the Agency will remove all references to animal dusting and will revise all product labels, accordingly.

Homeowner scenarios 2 and 3 are for dog dipping and using a dog collar, respectively. The Agency will remove all references to these uses and will revise all product labels, accordingly.

L. SPAH ORE Comment 12: Detailed Items, Page 25 (Page 3 of letter)

i. SPAH Comment 12

Page 25, Residential Post Application Exposure Assessment. Contact with treated pets, this is actually contact with treated dogs, and since there are more cats than dogs in the U.S. there could be a significant reduction in the potential exposure. This also applies to scenarios [3] and [4].

ii. Agency Response to SPAH Comment 12

The Agency acknowledges the dog and cat population values presented in this comment. The Agency also acknowledges that the total number of exposure events is probably less than would be expected if both cats and dogs were treated with phosmet. These population estimates, however, do not impact the results of the short- and intermediate-term risk assessment that were completed for phosmet use on dogs. The focus of short- and intermediate-term non-dietary risk assessment is to consider the daily risks for a single individual after the use of a product. In these assessments, daily exposure values are calculated with no adjustment for the number of animals treated throughout the country as the focus of the assessment is the exposure of an "individual" after a single use. This adjustment would not be appropriate as the dose calculated for the exposed individual reflects the dose attributable to a use event and does not consider the probability of use (i.e., a percent animal treated value is not appropriate in order to dilute the dose rate).

The additional comment that "this also applies to scenarios [3] and [4]" is in error as it is believed by the Agency that the author intended to introduce scenarios [1] and [2]. The same issue of dose dilution based on percent crop treated for home garden (pear tree) maintenance also applies to this scenario.

M. SPAH ORE Comment 13: Detailed Items, Page 27 (Page 3 of letter)

i. SPAH Comment 13

Page 27, General Risk Characterization Considerations/Issues. Consideration of the livestock dust scenario and the livestock dipping scenario should be discarded since these are no longer currently registered uses. To assist the Agency reviewers in understanding "backrubbers", their construction and use an article entitled "A Backrubber to Control Buffalo Flies" from the Queensland Department of Primary Industry is attached.

ii. Agency Response to SPAH Comment 13

The Agency refers to Sections 3.D and 3.K above where it is acknowledged by SPAH that a dip vat use still exists, but that they will likely be canceled. As a result, the Agency will not remove these uses from the risk assessment until all cancellations of such products become official. Additionally, the Agency will remove all references to animal dusting and will revise all product labels, accordingly.

With regard to the comments on the backrubber risk assessment, no use information prior to the Queensland article had been submitted to the Agency by SPAH. The construction and use of a backrubber detailed in the article is not significantly different from that envisioned by the Agency. The article indicates (in the "Costs" section) that a rubber could be used to support 100 head of cattle. Using this as a basis, it is likely that a typical grower would use and maintain several rubber devices because cattle herds, particularly in large production states like Florida and Texas, can be significantly larger than 100 animals. The Agency risk assessment is based on the preparation of 40 gallons of fuel oil/phosmet solution that is used to charge the backrubber devices (i.e., 1 gallon of phosmet formulation is required). The Queensland article indicates that "the first charging of a new rubber requires 11 L of oil mixture which is poured on in strips along the rubber" (Note: The article is based on charging backrubber devices with diazinon and not phosmet). Using this volume per rubber device and the premise that each rubber will treat 100 head of cattle, the Agency determined that approximately 14 rubber devices can be initially "charged" with 40 gallons of solution which equates to a herd size of approximately 1400 head. This is a reasonable herd size. It is also likely that ranchers may prepare larger quantities of the fuel oil/phosmet mixture and store it between backrubber charging events. The Agency would also like to indicate that no use-specific exposure data were submitted by SPAH and that the Agency clearly indicated in Table 4 of Appendix A of the ORE RED Chapter document that the assessment of backrubber exposures should be considered low confidence or rangefinder in nature -- the Agency completed the assessment because phosmet animal uses are significant and the only alternative is to indicate that no data exist. In fact the RED Chapter indicated the following:

"No empirical [exposure] data are available for this scenario. Instead, open mixing/loading of liquids data were used to complete this assessment. The assessment must be considered for use only as a rangefinder using extremely low confidence data because of the extrapolation that has been completed."

The Agency believes that there is more to the preparation and use of a cattle backrubber device than the open vat preparation of a fuel oil/phosmet solution. The open mixing/loading liquids exposure value that was used does not account for "charging" the backrubber device with the fuel oil mixture or placement/adjustment of backrubber devices in the field. It is believed that these aspects of the use pattern may contribute significantly to the overall exposure. Therefore, the Agency will not revise the backrubber risk assessment until additional use-specific exposure data become available in order to refine assessment to account for charging and placement of the backrubber devices.

N. SPAH ORE Comment 14: Detailed Items, Page 27 (Page 4 of letter)

i. SPAH Comment 14

Page 27: Summary of Total Risks to Occupational Handlers Scenarios. The livestock dipping scenario is irrelevant since there are no currently registered uses.

ii. Agency Response to SPAH Comment 14

The Agency refers to the SPAH comment and Agency response in section 3.D above in which SPAH acknowledged that an animal dip vat use still exists and has not been canceled to date.

O. SPAH ORE Comment 15: Detailed Items, Page 28 (Page 4 of letter)

i. SPAH Comment 15

Page 28, Summary of Total Risks to Occupational Handlers Scenarios. Again the cattle dust bag scenario is irrelevant, there is no such registered use. *Occupational use of dog collars is also irrelevant since this use will be voluntarily canceled shortly.*

ii. Agency Response to SPAH Comment 15

The Agency refers to the SPAH comment and Agency response in section 3.B, 3.I, and 3.K above.

P. SPAH ORE Comment 16: Detailed Items, Page 34 (Page 4 of letter)

i. SPAH Comment 16

Page 34, Residential Risks From Postapplication Exposures. again, the reference [to] large

and small pets instead of dogs.

ii. Agency Response to SPAH Comment 16

The Agency refers to the SPAH comment and Agency response in section 3.C above.

Q. SPAH ORE Comment 17: Detailed Items, Page 34 (Page 4 of letter)

i. SPAH Comment 17

Page 34, Incident Reporting Data. A summary should have been included since I believe such data regarding livestock uses would be very useful since I doubt if there were many reportable incidents of adverse reactions to humans or domestic animals caused by such use. With regards to pet uses, we know from meetings at the Agency that according to Dr. Jerome Blondell there have been "hundreds: of human exposure incidents reported through 6[a][2]. The risk of organophosphate poisoning by exposure to phosmet products labeled for use on dogs has been ameliorated by SPAH's cancellation of Del-Phos Sponge-On Dip for Dogs product, and Wellmark's cancellation of its OTC dog dip product.

ii. Agency Response to SPAH Comment 17

An incident report analysis for phosmet was completed by Dr. Jerome Blondell of the Agency (dated December 7, 1998, entitled *Review of Phosmet Incident Reports*, DP Barcode D251427). This report concludes "the majority of the more serious cases involved systemic illnesses to pet owners, groomers, and veterinary assistants who were not properly protected and experience illnesses while treating dogs for fleas, which is a misuse of the product." It is the standard practice of the Agency to incorporate epidemiological analyses in risk management decisions. Further analysis of available incident data may be required to address SPAH comments regarding phosmet livestock uses.

R. SPAH ORE Comment 18: Detailed Items, Appendix A/Table 1 (Page 4 of letter)

i. SPAH Comment 18

Entries relating to mixing/loading to fill/recharge dip vats should be removed. Similarly, references to applying by using a dip vat for livestock and to dusting livestock and *use of a dog collar* [including those in table footnotes] should be removed. In table footnote c there are errors in relevant EPARN's. All references to 773-77, 773-79, 2724-277 and 2724-279 should be removed. In addition all references to EPARN's with company number 59 should be converted into the correct 773 EPARN since Coopers Animal Health Inc registrations were transferred to Mallinckrodt Veterinary Inc., and subsequently to SPAH. The above comments are also applicable where relevant to Tables 2, 3, 4, 5, and 6.

ii. Agency Response to SPAH Comment 18

The Agency refers to its responses above that address the registration status of several phosmet uses. The Agency reiterates that only officially canceled uses will be removed from the risk assessment and that the Agency will not remove uses from the risk assessment until all cancellations of such products become official.

- S. SPAH ORE Comment 19: HED Human Risk Assessment, Page 1 (Page 4 of letter)
 - i. SPAH Comment 19

Page 1, Background. References to dusts and treated articles should be removed.

ii. Agency Response to SPAH Comment 19

The Agency refers to its response in Section 3.I above with the stipulation that treated articles refers to dog collars.

- T. SPAH ORE Comment 20: HED Human Risk Assessment, Page 11 (Page 4 of letter)
 - i. SPAH Comment 20

Page 11, Occupational Exposure. Again pets is said to include dogs and cats when in fact there is no registered use on cats.

ii. Agency Response to SPAH Comment 20

The Agency refers to its response in Section 3.C above.

- U. SPAH ORE Comment 21: HED Human Risk Assessment, Page 18 (Page 4 of letter)
 - i. SPAH Comment 21

Page 18, Postapplication Exposure and Risk. The last paragraph on this page should be removed, it is in part erroneous and completely irrelevant since [a] it serves no purpose, [b] no phosmet product was labeled for use on cats after March 2, 1988, and [c] the product registration has been voluntarily canceled.

ii. Agency Response to SPAH Comment 21

The Agency refers to the SPAH comment and its response in Section 3.B above. All references to this label will be removed from the risk assessment pending verification of the regulatory status. The Agency agrees that the placement of this paragraph describing animal incident rates is in error and that it should be integrated into a separate section. The purpose of this paragraph is to document pet incident rates, which pending a decision on regulatory status, is germaine to the use of a pet treatment product. The reference to cats is confusing to the Agency since there is no mention of cats in the paragraph and pomeranians are small, toy-type dogs.